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January 4, 2001



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: **Docket No. 00N-1567**
Agency Information Collection Activities; Proposed Collection; Registration of
Producers of Drugs and Listing of Drugs in Commercial Distribution


Merck & Co., Inc. is a leading worldwide, human health product company. Merck's corporate strategy -- to discover new medicines through breakthrough research -- encourages us to spend more than \$2 Billion annually, on worldwide Research and Development (R & D). Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the important pharmaceutical products on the market today.

As an innovative research and development company, Merck is affected by regulations which impact reporting requirements and therefore, we are interested in and qualified to comment on this Federal Register Notice. This notice solicited comments on collection activities governing the registration of producers and listing of drugs in commercial distribution.

According to Table 1, which lists estimated annual reporting burdens, the hours per response for drug product listing (FDA Form 2657) is estimated at 0.5 hours. Our experience is that the average time required per response for drug listing submission is approximately 4 hours as opposed to the 0.5 hours cited. The time represents the collection of and validation of the information, completion of the form and preparation of correspondence to the Agency.

We appreciate the opportunity to provide comments and are supportive of any Agency initiative, such as electronic submissions for drug listing that could potentially reduce the burden for collection of this information.

Sincerely,


Dennis M. Erb, Ph.D.
Senior Director
Regulatory Affairs

q:In-line products/fr/dla

00N-1567

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